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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,811	NOGAMI, EIJI	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-12 and 14-21* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-10 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/12/09, 4/7/09, 4/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on February 9 2009 and March 9 2009 have been entered.

Receipt of Amendments/Remarks filed on March 9 2009 is acknowledged. Claims 3, 6 and 13 were/stand cancelled. Claims 1-2, 4-5, 16-17 and 21 were amended. Claims 1-2, 4-5, 7-12 and 14-21 are pending. Claims 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 8 2007. Claims 1-2, 4-5, 7-10 and 14-21 are directed to the elected invention.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 3/12/09, 4/7/09 and 4/30/09 were considered by the examiner.

Claim Objections

The objection of claim because of the following informalities: the examiner believes that parastalsis is incorrectly spelt and should correctly be spelt as peristalsis is **withdrawn** in light of Applicant's deletion of the term from the claim in the reply filed on February 9 2009.

Withdrawn Rejections

The rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in light of Applicant's deletion of the term from the claim in the reply filed on February 9 2009.

The rejection of claims 4-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicant's amendment in the reply filed on February 9 2009.

The rejection of claims 1-2, 4-5, 7-10 and 14-16 under 35 U.S.C. 103(a) as being unpatentable over Yamamura et al. (US Patent No. 5914118) is **withdrawn** in light of Applicant's amendments in the reply filed on March 9 2009.

The rejection of claims 17-21 under 35 U.S.C. 103(a) as being unpatentable over Takayanagi et al. (US Patent No. 4765983) in view of Kuroya et al. (US Patent NO. 5137729) and Geoghegan et al. (US Patent No. 6641839) is **withdrawn** in light of Applicant's amendments in the reply filed on March 9 2009.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-5, 7-10, 14-16 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant application claims the orally administered agent is free of a bioadhesive layer. However, instantly claimed and taught polymers for formation are known to be adhesives.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable

> amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Formal, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, relative skill level, and breadth of the claims

The instant invention is directed to an orally administered agent free of a bioadhesive layer. The instant claims recite the incorporation of a water-swellable gel-forming layer which comprise a water-swellable gel forming agent and a film-forming

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is

agent. Specific polymers claimed is carboxyvinyl polymer crosslinked by a polyvalent metal compound and polyvinyl alcohol. Other polymers taught as being included in the layers are cellulose and/or cellulose derivative.

The specification generally teaches that edible polymer (cellulose and/or cellulose derivatives) include hydroxypropyl cellulose, hydroxypropyl methyl cellulose phthalate. Water swellable gel forming agents include crosslinked and non crosslinked carboxy vinyl polymers, starches and derivatives thereof, agar, alginic acid, arabinogalactan, galactomannan, cellulose and derivatives thereof, carrageen, dextran, tragacanth, gelatin, pectin, hyaluronic acid, gellan gum, collagen, casein, and xanthan. Examples of film-forming agents include polyvinyl alcohol, polyvinyl pyrrolidone, polyvinyl acetate, polyvinyl acetate phthalate, hydroxyalkyl celluloses (e.g. hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxymethyl cellulose, hydroxyethyl cellulose), alkyl celluloses (e.g. methyl cellulose, ethyl cellulose), carboxyalkyl celluloses (e.g. carboxymethyl cellulose), (meth)acrylic acid and esters thereof, xanthan gum, carrageenan, and alginic acid.

The relative skill of those in the art is high, that of an MD or PHD.

The state and predictability of the art

The state of the art recognizes certain polymers are bioadhesive and/or mucoadhesive. As illustrative of the state of the art, the examiner cites Heiber et al. (US Patent No. 5766620) and Friedman et al. (US Patent No. 5993846).

"undue", not "experimentation".

Heiber et al. teach that "adhesive," "adhesive polymer", "mucoadhesive", or such similar terms refers to hydrophilic polymers, natural or synthetic, which, by the hydrophilic designation, can be either water soluble or swellable. Such adhesives function for adhering the dosage forms to the mucous tissues of the oral cavity, such as the gingiva. Such adhesives are inclusive of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxy ethyl cellulose, ethyl cellulose, carboxymethyl cellulose, dextran, gaur gum, polyvinyl pyrrolidone, pectins, starches, gelatin, casein, acrylic acid polymers, polymers of acrylic acid esters, acrylic acid copolymers, vinyl polymers, vinyl copolymers, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers, and mixtures thereof, and the like (column 11, lines 19-34).

Friedman et al. teach that bioadhesive polymers include carboxymethylcellulose (CMC), hydroxypropylmethylcellulose (HPMC), polyacrylic and polymethacrylic acid and their derivatives, pectin, alginic acid, chitosan, polyvinylpyrrolidone, hyaluronic acid, and polyvinylalcohol (column 1, lines 36-45).

The amount of direction or guidance provided, the presence or absence of working examples and the quantity of experimentation necessary

The specification provides no direction or guidance for formulating a multilayered orally administered that is free of a bioadhesive layer when the layers are comprised of polymers that are known in the art to be bioadhesive/mucoadhesive. The specific polymers taught in the specification overlap substantially with those taught in the art as being bioadhesive/mucoadhesive. The instant specification provides no guidance as to how the layers are formulated and are not bioadhesive/mucoadhesive. Therefore, one

of ordinary skill in the art would have to undergo an undue amount of experimentation in order to determine how to formulate orally administered agents which are free of a bioadhesive layer as the instantly taught polymers are known in the art to be mucoadhesive/bioadhesive.

Conclusion

Therefore, because the instant specification provides no guidance as to the formulations of an orally administered agent that is free of a bioadhesive layer which comprises polymers that are known in the art to be bioadhesive/mucoadhesive, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to form multilayered orally administered agents that are free of a bioadhesive layer as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claims 2 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 2 and 21 have been amended to recite that the "film forming agent of the water-swellable gel-forming layers is adjustable to modify a film strength forming agent of the water-swellable gel-forming layers to correspond to a thickness of the drug-containing layer". In the response filed on March 9 2009 it was indicated that support could be found on page 8, lines 6-20 and page 16 lines 11-25. The passage on page 8 indicates that the medicinal agent is constituted from a plurality of layers and may have any shape, ...that by processing into a film shaped preparation the moisture content in the preparation can be kept low and hence the stability of the drug contained in the preparation can be increased, ...and layer(s) for adjusting the film thickness may be provided as layer(s) other than the drug containing layer(s) and the water-swellable gel forming layer(s). It is taught that providing such layer(s) and then increasing the film thickness there is ease of handling. The passage on page 16 indicates that even if the drug content in the drug-container layer(s) increase and thus films strength of this layer drops, the strength of the preparation as a whole can still be maintained by giving the water-swellable gel-forming layer(s) film-forming properties. Therefore, in essence these sections indicate that thickness of the layers may be adjusted and that by giving the water-swellable gel forming layers film forming properties the film strength of the preparation as a whole can still be maintained. However, these sections do not provide support for a relationship between the thickness of the drug-containing layer and the film strength of the water swellable gel-forming layers. Therefore, the recitation of "the film forming agent of the water-swellable gel-forming layers is adjustable to modify a film strength forming agent of the water-swellable gel-forming layers to correspond to a

thickness of the drug-containing layer" is deemed new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2 and 21, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 2 and 21 as currently written are vague and indefinite. The claims recite that the "water-swellable gel-forming layers is adjustable to modify a film strength forming agent of the water-swellable gel-forming layers to correspond to a thickness of the drug-containing layer" which is confusing. While adjusting the film forming agent of the water-swellable gel-forming layers to modify the film strength is not by itself indefinite, it is unclear what this has to do with the thickness of the drug-containing layer nor how it corresponds to the thickness of the drug-containing layer. The instant specification provides no explanation as to the relationship between the thickness of the drug-containing layer and the film-strength of the water-swellable layers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-5, 7-10 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edgren et al. (US Patent No. 6797283) in view of Gruber (WO 9806385).

Applicant Claims

The instant application claims an orally administered agent free of a bioadhesive layer comprising a drug-containing layer including a drug; a first water swellable gel-forming layer provided on one side of the drug containing layer; a second water-swellable gel-forming layer provided on the other side of the drug-containing layer; wherein the first water-swellable gel-forming layer and the second water-swellable gel-forming layer contain a water-swellable gel-forming agent and a film-forming agent the concentration of the water-swellable gel-forming agent in the first water sellable gel forming layer or the second water swellable gel forming layer is 15 to 70 wt. % and the

content of the film forming agent in the first or second water swellable gel-forming layer is 30 to 85 wt. %.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Edgren et al. is directed to a gastric retention dosage form having multiple layers. The active agent dosage form adapted for gastric retention comprising a first layer comprising a swellable water soluble polymer and a second layer comprising a therapeutically effective amount of an active agent, the second layer being laminated with the first layer at a common surface (column 5, lines 9-14). It is taught that a soluble coating may be applied to the two layers prior to the banding process to provide a smooth surface that facilitates swallowing of the dosage form (column 8, lines 58-61). Examples of swellable polymer are hydroxypropyl cellulose, hydroxypropyl methyl cellulose, polyvinyl alcohol, gelatin, sodium polyacrylic acid, calcium polyacrylic acids, etc. (columns 8-9, lines 64-67 and 1-62). The second layer preferentially includes a hydroattractant (column 10, lines 30-39). Particularly suitable hydroattractant is hydroxypropyl cellulose (column 10, lines 51-52). The swellable polymer in the first layer is preferably in an amount of 60 to 100 weight percent. The hydroattractant, hydroxypropyl cellulose, is preferably in an amount of about 10 to about 60 weight percent (column 27, lines 4-12). Example 3 utilizes polyvinyl alcohol as the swellable polymer.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

While Edgren et al. teach that both calcium polyacrylic acids and polyvinyl alcohol are suitable swellable polymers, Edgren et al. do not exemplify utilizing both calcium polyacrylic acids and polyvinyl alcohol in the formation of the first layer.

While Edgren et al. teach a coating can go around the layers in order to provide a smooth surface that facilitates swallowing of the dosage form, Edgren et al. do not specify the components of this coating. However, this deficiency is cured by Gruber.

Gruber (wherein US PGPUB No. 2002/0068088 is serving as the English language equivalent to WO 9806385) is directed to easy to swallow oral medicament composition. It is taught that the coating layer contain at least one hydratable pharmaceutically acceptable polymer which on contact with saliva or water forms a coherent moldable viscous mass which is slippery on the surface and does not adhere to the oral mucosa and which prevents active ingredient containing particles from escaping from the mass and release of the active ingredient in the mouth (paragraph 0017). The hydratable polymers overlap those taught by Edgren as the swellable polymers (paragraph 0027 and 0030). It is taught that the proportion of hydratable polymer in the coating may vary within certain limits depending on the polymer used. Optimal amounts can easily be determined from case to case by adding water or saliva. Outmost layers are usually about 1 to 30% by weight of hydratable polymer (paragraph 0039).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Edgren et al. and Gruber and utilize a

coating comprising hydratable polymer(s). One of ordinary skill in the art would have been motivated to utilize a coating with hydratable polymer(s) as Edgren et al. teach that the coating can go around the layers in order to provide a smooth surface that facilitates swallowing of the dosage form and Gruber teach that coatings comprising hydratable polymers which on contract with saliva or water form a coherent moldable viscous mass which is slippery on the surface and prevents the active ingredient from being released in the mouth. Therefore Edgren et al. teach that coatings comprising hydratable polymers accomplish what the coating of Edgren et al. is designed to do, i.e. make it easier to swallow the orally administered dosage form.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Edgren et al. and Gruber and utilize both calcium polyacrylic acid (which is a crosslinked carboxyvinyl polymer) in combination with polyvinyl alcohol. One of ordinary skill in the art would have been motivated to utilize both as Edgren et al. exemplify utilizing polyvinyl alcohol and teach calcium polyacrylic acid as another suitable swellable polymer. Since Gruber teaches that the proportions of the hydratable polymer vary depending on the polymer utilized and both are taught as suitable, it would have been obvious to one of ordinary skill in the art to utilize the combination in order to manipulate the formulation in order optimize the delivery of the active agent. It would have been obvious to one of ordinary skill in the art to try the specifically taught swellable polymers as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP**

2141 [R-6] *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).

Regarding the claimed amount of the edible polymer, Edgren et al. teach an amount that overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

Regarding the claimed shape of the preparation, this is design choice and imparts no criticality to the invention and is a matter of choice to one of ordinary skill.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US Patent No. 6120802) in view of Gruber.

Applicant Claims

The instant application claims an orally administered agent having a structure comprising a plurality of drug containing layers and water-swellable gel-forming layers wherein the multiple drug containing layers are heat sealed via an intermediate layer which includes a heat-sealing adhesive and the water swellable gel forming layers are

provided as outmost layers of the orally administered agent to cover the drug containing layers.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Breitenbach et al. is directed to a method of producing multi-layer medicaments in solid form for oral or rectal administration. The drug form which is produced preferably comprise two or three layers and at least one of layers contains at least one pharmaceutical active ingredient. It is possible for another active ingredient to be accommodated in another layer (column 2, lines 59-67). The thickness is chosen depending on the required release characteristics (column 3, lines 6-9). The layers comprise at least one thermoplastic pharmacology acceptable polymer binder which combine due to melting or softening pasty or viscous and therefore extrudable. Preferred binders include copolymers of N-vinylpyrrolidone and vinyl esters (especially vinyl acetate) (column 3, lines 30-65). Layers containing no active ingredient are also contemplated (column 3, lines 66-67). The multilayer drug forms can be rounded and/or provided with a coating (column 7, lines 26-30).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

While Breitenbach et al. teach a coating can be applied, Breitenbach et al. do not teach specific coatings or one comprised of water-swellable gel forming layers. However, this deficiency is cured by Gruber.

Gruber (wherein US PGPUB No. 2002/0068088 is serving as the English language equivalent to WO 9806385) is directed to easy to swallow oral medicament

composition. It is taught that the coating layer contain at least one hydratable pharmaceutically acceptable polymer which on contact with saliva or water forms a coherent moldable viscous mass which is slippery on the surface and does not adhere to the oral mucosa and which prevents active ingredient containing particles from escaping form the mass and release of the active ingredient in the mouth (paragraph 0017). It is taught that the proportion of hydratable polymer in the coating may vary within certain limits depending on the polymer used. Optimal amounts can easily be determined from case to case by addition water or saliva. Outmost layers are usually about 1 to 30% by weight of hydratable polymer (paragraph 0039).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Breitenbach et al. and Gruber and utilize a coating layer comprising at least one hydratable polymer. One of ordinary skill in the art would have been motivated to utilize a coating layer comprising at least hydratable polymer as Breitenbach et al. teach coatings can be applied and Gruber teach coatings comprising hydratable polymers forms a coherent moldable viscous mass which is slippery on the surface and prevents active ingredient containing particles from escaping from the mass and release of the active ingredient in the mouth. Therefore, the coating taught in Gruber serve to not only make the device easier to swallow but also mask the taste of the active ingredient.

Regarding the claimed shape of the preparation, this is design choice and imparts no criticality to the invention and is a matter of choice to one of ordinary skill.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-5, 7-10 and 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11540952. Although the conflicting

claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims an orally administered agent comprising an edible polymer layer containing a drug; a first water-swellable gel forming layer on one side of the drug-containing layer and a second water-swellable gel-forming layer provide don the other side of the drug-containing layer wherein the first water-swellable layer and second water-swellable layer contain a water-swellable gel-forming agent and a film-forming agent. The amount of water-swellable gel-forming agent in the first water-swellable gel forming layer or second layer is 15 to 70 wt% and the content of the film-forming agent in the first water-swellable gel-forming layer or second layer is 30 to 85%.

Copending '952 claims an orally administered pharmaceutical composition comprising a first water-swellable gel-forming layer, a second water-swellable gel-forming layer. These layers enclose a drug-containing layer.

Copending '952 does not claim particular polymers utilized in the water-swellable gel forming layers or the drug-containing layer. Copending '952 does not claim particular amounts of polymers utilized in the layers.

Therefore, the relationship between the instant application and copending '952 is a genus-species relationship. Carboxyvinyl polymer is a particular type of water-swellable gel-forming agent.

Regarding the claimed amounts of polymer, it would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Therefore, both the instant application and copending '952 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 17-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10592953. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims an orally administered agent comprising a plurality of drug-containing layers and a water swellable gel-forming layer wherein the drug-containing layers are heat sealed via a layer comprising a heat-sealing adhesive.

Copending '953 is directed to a method for producing a pharmaceutical composition comprising a first functional layer provided to one side of a drug-containing layer and a second functional layer. The drug containing layer comprises a thermoplastic polymer as a base. As claimed there can be multiple intermediate drug containing layers. The functional layers are formed from water-swellable gel-forming

layers. The thermoplastic edible polymers include polyvinylpyrrolidone, vinylpyrrolidone-vinyl acetate copolymer and polyvinyl acetate.

Copending '953 is directed to the method of producing a pharmaceutical composition. The pharmaceutical composition produced is the same as that instantly claimed. Therefore, both the instant application and copending '953 are directed to similar subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed February 2 2009 are acknowledged. The rejections are maintained since applicant has not made any substantive arguments traversing the rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616